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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KHANNA, HEMANT	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,376	SABETSKY, VLADIMIR	
	Examiner	Art Unit	
	Hemant Khanna	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-25 and 38-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of claims 26-37 that belong to Group II in the reply filed on November 03, 2006 is acknowledged. The traversal is on the ground(s) that the inventions covered in the withdrawn claims that belong to the method Group III (Second paragraph, Response) is sufficiently related that a thorough search for the subject matter of any claim within Group II would encompass a search for the subject matter of the remaining claims in Group III.

The restriction for Groups I-III is maintained. The applicant's state that the inventions of Group II (elected with traverse) and Group III (method of making) are both classified in class 424.

The applicant's arguments are not found persuasive because while the inventions of Group II and Group III are classified in the same class, the inventions are classified in different subclasses. Further, the applicant is reminded that the invention of Group II (composition of matter) belongs to a statutory class distinct from the invention of the invention of Group III (process). Additionally, as set forth in the Examiner's requirement for restriction filed on October 03, 2006, the inventions of Group II and III are independent or distinct because "the product of a dosed pharmaceutical composition can be undertaken by incorporating insulin into dextran microparticles using a layer-by-layer adsorption of oppositely charged electrolytes".

Further, the inventions of Group I and Group II are drawn to pharmaceutical compositions and a method of lowering blood glucose, which are not obvious variants of

each other. Thus, by virtue of their divergent subject matter, and because searching one invention would not be co-extensive with searching the other, the inventions of Groups I, II and III are distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-40 are pending.

Claims 1-25, 38-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **with** traverse in the reply filed on November 03, 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 26-27, 29-32, and 36-37, rejected under 35 U.S.C. 103(a) as being unpatentable over Schroder. (USPN 4,713,249) in view of Ecanow (USPN 4,963,526).

The instant claims are drawn to a dosed pharmaceutical composition, comprising dextran microparticles held together by non-covalent bonds, in presence of a therapeutically effective amount of insulin, wherein the composition is located in a vessel with instructions printed on the vessel for oral dosage.

With respect to claims 26-27, Schroeder teaches prolonged release compositions for the delivery of biologically active substances, such as insulin (Example 13) consisting of a carbohydrate microsphere, such as dextran (column 3, lines 4-20; Example 1), wherein the carbohydrate is stabilized by crystallization (abstract). Schroeder further teaches that in crystallization, the types of bonds holding the carbohydrate polymers are non-covalent of the type hydrogen bonds or vander Waals forces (column 2, lines 55-60). Schroeder also teaches that during the preparation of the composition, the carbohydrate polymer is dissolved in a pharmaceutically acceptable solvent, such as water (column 3, lines 60-70). Schroeder also discloses that the average diameter of the spheres is within a range of 0.01 microns to 1000 microns.

Schroeder differs from claims 29-32, and 36-37 by not specifically disclosing that the composition is a tablet or capsule and is located within a vessel with instructions on the vessel for administration.

With respect to claims 29-32, and 36-37, Ecanow discloses that it is known in the art to provide a composition in oral dosage form such as capsules, tablets or a liquid vehicle (claim 35) wherein a dose of insulin is useful for introduction in the bloodstream via the oral dosage form (claim 36).

In view of this teaching it would have been obvious to one of ordinary skill in the art to secure the composition comprising the dextran microparticle and insulin in a

vessel with instructions for the known and expected result of providing a means recognized in the art to administer insulin orally.

4. Claims 28, 33-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Schroder (USPN 4,713,249) and Ecanow as applied to claim 26-27, 29-32, and 36-37 above and further in view of Moriyama (Journal of Controlled Release (1996) 42:237-248, as cited in the IDS filed on August 20, 2006).

The instant claims are drawn to a dosed pharmaceutical composition, comprising dextran microparticles and a therapeutic amount of insulin, wherein the composition comprises two phases of dextran and PEG, and further wherein the insulin is selectively partitioned in the PEG phase. The instant claims are also drawn to a kit comprising an aqueous suspension of the microparticles and insulin located within a vessel.

With respect to claims 28, and 33, Schroeder teaches prolonged release compositions for the delivery of biologically active substances, such as insulin (Example 13) consisting of a carbohydrate microsphere, such as dextran (column 3, lines 4-20; Example 1), wherein the carbohydrate is stabilized by crystallization (abstract). Schroeder further teaches that in crystallization, the types of bonds holding the carbohydrate polymers are non-covalent of the type hydrogen bonds or vander Waals forces (column 2, lines 55-60). Schroeder also teaches that during the preparation of the composition, the carbohydrate polymer is dissolved in a pharmaceutically acceptable solvent, such as water (column 3, lines 60-70). Schroeder also discloses

that the average diameter of the spheres is within a range of 0.01 microns to 1000 microns.

Schroeder differs from claims 28, and 33 by not specifically disclosing an aqueous suspension of dextran microparticles and a therapeutically amount of insulin, which is selectively partitioned in the PEG phase.

With respect to claims 28, and 33, Moriyama discloses that it is known in the art to distribute proteins in a two-phase system by mixing aqueous solutions in phosphate buffer of two different water soluble polymers, such as PEG and dextran, and insulin, wherein the negatively charged insulin is preferentially partitioned into the PEG phase (second paragraph, page 238; Figure 1)

In view of this teaching it would have been obvious to one of ordinary skill in the art to secure a two phase composition comprising the dextran phase and the PEG phase for the known and expected result of providing a means recognized in the art to enable the formulation of peptide drugs into biodegradable polymers such as dextran containing PEG, wherein the distribution of insulin in PEG would prevent the diffusion of insulin in the dextran matrices.

With respect to claims 34-35, Ecanow discloses that it is known in the art to provide a composition in oral dosage form such as capsules, tablets or a liquid vehicle (claim 35) wherein a dose of insulin is useful for introduction in the bloodstream via the oral dosage form (claim 36).

In view of the above teaching, a kit comprising a pharmaceutical composition of aqueous dextran microparticles and insulin, would have been merely an obvious matter

of packaging the composition in kit form because kits are routinely used in the pharmaceutical arts for the purposes of storage, transportation, measurement and administration.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hemant Khanna
November 21, 2006

B. DELL CHISM
PRIMARY EXAMINER